REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks and amendments herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 27-36, 38 and 47 are now pending. Claims 27 and 47 have been amended, and claims 37, 39 and 45 have been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is respectfully submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply to place the claims in better condition for examination.

II. THE REJECTIONS UNDER 35 USC §112 ARE OVERCOME

Claims 27-39, 45 and 47 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement for a pharmaceutical composition for the treatment of any disease or condition. The rejection is respectfully traversed.

Initially, Applicants note that claim 45 has been cancelled herein, without prejudice. The remaining claims relate to a peptide comprising a sequence selected from SEQ ID NOs: 1-3 or a functional variant thereof, wherein the functional variant contains at least six amino acids and is at least 80% identical to one of SEQ ID NOs: 1-3 and which retains its ability to bind to a causative agent of a disease or a disorder, said causative agent having SOD activity, and inhibit the causative agent's SOD and/or metal binding ability.

35 U.S.C. §112, first paragraph, requires that the specification describe how to make and use the invention. 35 U.S.C. §112, first paragraph, recites, in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.]

A patent claim is invalid if it is not, *inter alia*, supported by an enabling disclosure. The test for enablement requires a determination of whether any person skilled in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400, (Fed. Cir. 1988). The factors involved in determining whether there is sufficient evidence to support a finding of enablement include, among others, (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the level of one of ordinary skill, (5) the level of predictability in the art, (6) the amount of direction provided by the inventor, (7) the existence of working examples, and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *See Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404.

The Office Action states that the rejection has been applied to the non-pharmaceutical composition claims because claim 27 was amended to "include a functional recitation of binding agents that are causative in disease". Office Action at 3. Applicants disagree with this reasoning.

Regardless of the functional recitation, claims 27 to 36 are **not** directed to pharmaceutical compositions, they are merely directed to **peptides** which bind to a causative agent of a disease and inhibit that causative agent's ability to bind SOD or a metal. Claims 27 to 36 do not claim that all such sequences are, or should be, therapeutic. Furthermore, it is not claimed that all the compounds *can* bind a causative agent; rather, the claims are only directed to those compounds that *do* bind and cause inhibition. The functional recitation, therefore, is present to cull from the larger group of peptides those which are claimed in the present invention. That such peptides may be used in a therapeutic setting is not required by the pending claims.

Nevertheless, attached as Exhibit A is supporting data which indicates that SEQ ID NOs:1-3 are able to specifically reduce H202 production by human Aβ1-42 and thus modify Aβ1-42 's SOD-like activity and block neurotoxicity in M17 cells. In addition, SEQ ID NO:3 is also shown to be able to attenuate or block Aβ1-42 induced LDH release by M17 cells. Although SEQ ID NO:3 was found to have more activity than the two 6-mers,all candidate peptides had some positive activity in the tests performed. Also provided in Exhibit A is a second study that shows that, in an acute rat model of Aβ toxicity, SEQ ID NO:3 was able to increase the clearance of Aβ from the rat brain.

Therefore, Applicants respectfully submit that the pending claims relate to peptides, not to pharmaceutical compositions, and the functional recitation of the claims serve only to further

define the claimed subject matter and are not indicative of therapeutic properties. However, Applicants have also provided as Exhibit A data showing that the peptides of the present invention have the activity described in the claims and the specification.

Therefore, the application is clearly enabled. The breadth of the claims is supported by the specification, the level of one of skill in the art is high, Applicants have provided sufficient guidance to allow one of skill in the art to make and use the claimed invention, including the data submitted herewith, and any experimentation undertaken by the skilled artisan would be merely routine and thus would not qualify as "undue".

For all of these reasons, reconsideration and withdrawal of the enablement rejections under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 26-39, 45 and 47 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement because the claims allegedly contain subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the invention at the time of filing. The rejection is respectfully traversed.

The Office Action alleges that the claims are "peptides of 80% identity to a peptide of SEQ ID NO: 3 and further deletion variants" that have "no length limits and no requirements of any relation in sequence structure." Office Action at 4-5. Further, it is alleged that terms such as "functional variants" or "peptidomimetics" are not defined in the specification such that they "could be anything" or are "readable upon virtually any sequence". Applicants respectfully disagree.

Claims 28-39 and 45 are all dependent on claim 27, which recites a peptide comprising a sequence selected from SEQ ID NO: 1-3, or a functional variant thereof which has **at least six amino acids** and is at least **80% identical** to the recited sequence and which retains its ability to bind to a causative agent of a disease or a disorder, said causative agent having SOD activity, and inhibit the causative agent's SOD and/or metal binding ability. Furthermore, claim 47 similarly requires that the variant have **at least six amino acids** and also requires that the polypeptide retains its ability to bind to a causative agent of a disease or a disorder, said causative agent having SOD activity, and inhibit the causative agent's SOD and/or metal binding ability

Thus, in view of the requirement of 80% identity, and the requirement of the peptide having at least six amino acids, Applicants respectfully submit that the short length of the

sequences in question results in a small pool of sequences which a skilled person would be able to routinely test. For example, only one amino acid at a time can be changed in SEQ ID NOs: 1 and 2, and only 3 amino acids can be changed in SEQ ID NO: 3. It would be entirely routine for one of skill in the art to test such small library of polypeptides to determine whether the sequences bind to the causative agent of the disease and stop the agent from binding SOD or the metal. Furthermore, only those compounds which fulfill all the criteria of being at least 80% identical, are able to bind to the causative agent and stop the causative agent binding to SOD or a metal are being claimed, thereby preventing the claims from reading "upon anything" or "virtually any sequence".

As to the term "functional variant", as stated above, the claims now encompass the recitation that such functional variants must be at least six amino acids in length. Support for such variants can be found, for example, on page 15, second full paragraph, of the specification as filed.

Applicants respectfully remind the Examiner that there is no requirement for all members of a class or group of compounds to be exemplified, merely a representative subset which allows the skilled artisan to understand the scope of the invention. Applicants respectfully submit that the three sequences exemplified in the present invention, along with the discussion of how to make variants of the same (e.g. by creating deletion variants or by locating sequences with 80% homology, as found in the specification as filed, for example at page 13, line 13 to page 15, line 10), would provide the skilled artisan with more than enough information to comprehend and routinely locate other peptides which fall within the scope of the invention. Thus, Applicants respectfully submit that the claims as currently written are supported by adequate written description in the specification, including as to functional variants.

In response to the rejection regarding the recitation of peptidomimetics in claim 38, Applicants submit that claim 38 has been cancelled herein, without prejudice, such that the rejection is moot.

Consequently, reconsideration and withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph, are respectfully requested.

III. THE ART REJECTIONS ARE OVERCOME

Claims 27-39 and 47 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Wakasugi et al. (1994). The rejection is respectfully traversed.

Applicants respectfully remind the Examiner that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.,* 3 U .S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

The Office Action states that "claim 27 is not limited to the full-length of SEQ ID NO: 3 and can be a fragment thereof". Consequently, the Office Action maintained the rejection based on Wakasugi et al. because Wakasugi et al. relates to "an exactly matching trimer (RNR) of the SEQ ID NO: 3." Office Action at 6.

Applicants respectfully submit that the pending claims require that any functional variants of SEQ ID NO: 3 contains at least six (6) amino acids, which thereby excludes the trimer of Wakasugi et al.

Accordingly, Wakasugi et al. fails to teach or suggest each and every element of the pending claims, such that the reference fails under Section 102.

Consequently, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner and his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the amendments, and remarks herein, the application is in condition for allowance. Reconsideration and withdrawal of the rejections of the application, and prompt issuance of a Notice of Allowance, is respectfully requested.

Respectfully submitted,

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